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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LIU, SAMUEL W	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/042,696	WILLIAMS ET AL.	
	Examiner	Art Unit	
	Samuel W Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-14 is/are pending in the application.

4a) Of the above claim(s) 2-7 and 9-14 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1 and 8 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 1-18-02.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. 8-2-04.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

Claims 1-14 are pending.

Election/restriction

Applicants' election of Group III, claim 8 with traverse in the response filed 28 June 2004 is acknowledged. The Traversal is on the ground(s) that (i) although Groups II, III and IV encompass different conjugates, they share the polypeptide set forth in claim 1 of Group I, and thus, Group II, II and IV are not distinct from one another (see page 7, the 3rd paragraph), and (ii) search all the claims would not place an undue burden on the Examiner (see page 8).

The applicants' argument is found unpersuasive because *chemotherapeutic drug* (e.g., doxorubicin – an anthracycline antibiotics) of Group II; *radioisotope* of Invention III; and *cytotoxic agent* (e.g., ricin – a toxic glycoprotein) are structurally and functionally distinct moieties which render the conjugated polypeptides comprising said moieties patentably distinct from one another. Note that chemical property of each conjugates are determined by entirety of the conjugated polypeptide (comprising a conjugate moiety and the claim 1 polypeptide moiety) but not by the said polypeptide moiety alone. Thus, they would be expected to exhibit different physical and chemical properties, and are capable of separate manufacture or use.

Regarding search burden, examining all the groups (all the claims) would require search additional search of all cytotoxic glycoprotein or toxin, e.g., ricin, abrin and diptheria toxin under class 514 if cytotoxic agent, i.e., Group IV were included, and

require search of inhibiting tumor cell metastasis by the polypeptide if Group V were included. Thus, co-examination of each Groups would be a serious burden of search.

It is of note that, on communication with Kathleen A. Tyrrell on August 2, 2004 (see the Interview Summary), Applicants agree to further elect claim 1 for examining the elected Group III (claim 8).

Therefore, elected claims 1 and 8 are examined in this Office action; and claims 2-7 and 9-14 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

IDS

The references cited in the IDS filed 18 January 2002 have been considered by Examiner.

Specification/Claim/ Objections

The disclosure is objected to because of the following informalities:

The CRF sequence listings filed 18 January 2002, 3 October 2001 and 15 April 15 2003 are object to as being inconsistency among them; for instance, SEQ ID NO:5 listed in the CRF sequence listings filed 18 January 2002 is the same as the peptide sequence of SEQ ID NO:3 listed in the CRF sequence listings filed 15 April 2003.

In page 3, line 3, "Cys-Ser-Val-Thr-Cys-Gly (SEQ ID NO:)", and line 4, "Cys-Ser-Val-Thr-Cys-Gly (SEQ ID NO:), lack the number of SEQ ID NO:_, respectively. The same correction should be made throughout the specification.

In page 31, line 8, "(i.e., (peptide1-peptide 2)" should be changed to "(i.e., peptide1– peptide 2)".

In page 43, the 2nd line from the bottom, "64μ" should be clarified.

In page 52, line 4 of the last paragraph, " ...or protein solution (HEPES buffered saline, pH7.4)" should be changed to "...or protein solution in HEPES buffer, pH7.4".

In page 55, line 4, "PHLC" should be changed to "HPLC".

In page 70, line 4, "EtOH" should be changed to "ethanol".

Appropriate correction is required.

Claim Rejection under 35 USC 101

35 U.S.C. §101 states:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 8 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claim 1 and the dependent claim 8 thereto, as written, do not sufficiently distinguish over polypeptides as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed polypeptide and the naturally occurring polypeptides. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

Claim Rejections - 35 USC § 112, the second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 1 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the claim recite "SEQ ID NO: without reciting sequence identifier number. Also, claim 1 sets forth "/" between terms, e.g., neutral/non-polar, and so on, which renders the claim unclear because "/" ambiguously refers to "or" or "and" or "or/and". Additionally, claim 1 appears to be missing 'and" before "Z_2". Further, claim 1 is unclear in "mimics or inhibits"; which one is it?

Claim Rejections - 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Deutch, A. H. et al. (US Pat. No. 5200397).

In the patent claims 3-4, Deutch et al. disclose a polypeptide formula (SEQ ID NO:20) which reads on the instant claim 1 formula, and each limitations for Xaa_2, Xaa_3,

Xaa_2, Xaa_4, Xaa_5, Xaa_6, Xaa_7, Xaa_8, Xaa_9, Xaa_{10}, Z_1 and Z_2 set forth in said formula meet the limitations of the instant claim 1. Thus, Deutch et al. anticipate the instant claim 1.

Also, Deutch et al. teach that the polypeptide (the compound) is labeled with a radioisotope, e.g., ^{125}I (see column 12, lines 8-12), which anticipates the instant claim 8.

Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Deutch, A. H. et al. (US Pat. No. 5190918).

In Example 4, Deutch et al. teach a thrombospondin polypeptide fragment (e.g., compound 11) which sequence is "WTSCSTSCG". This fragment reads on the core sequence "Xaa_2 –Xaa_3–Xaa_2–Xaa_4–Xaa_5–Xaa_6–Xaa_7–Xaa_8–Xaa_9–Xaa_{10}" of the formula set forth in claim 1 of the current application. The compound 11 fragment further comprises flanking sequences "WSPWSE" at N-terminus, and "NGIQQRGR" at C-terminus, which meets the claim 1 limitation that Z_1 and Z_2 is "*at least one amino acid residue*", respectively. Thus, the Deutch's teaching anticipates the instant claim 1.

Also, Deutch et al. teach that the said polypeptide (the compound) is labeled with a radioisotope, e.g., ^{125}I (see column 11, lines 38-43), which anticipates the instant claim 8.

Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Deutch, A. H. et al. (US Pat. No. 5426100).

In "*Preferred Embodiments*" section, Deutch et al. teach a polypeptide formula (also see the patent claim 1), wherein the limitations for each component (Xaa_2, Xaa_3,

Xaa_2, Xaa_4, Xaa_5, Xaa_6, Xaa_7, Xaa_8, Xaa_9, Xaa_{10}, Z_1 and Z_2) are the same as those set forth in the instant claim 1 formula. In addition, in Example 1, Deutch et al. teach compound P1 "WSPCSVTCG" which reads the formula of claim 1 and meets each limitations for the above-mentioned components. Thus, the Deutch et al. patent anticipates the instant claim 1.

Also, Deutch et al. teach that the said polypeptide (the compound) is labeled with a radioisotope, e.g., ^{125}I (see column 11, lines 59-64), which anticipates the instant claim 8.

Claim Rejection, 35 U.S.C. 101, Double Patenting

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process... may obtain a patent therefor..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1 and 8 are rejected under 35 U.S.C. 101 as claiming the same invention as claims 1 and 8 of prior U.S. Patent No.6339062, respectively. This is a double patenting rejection.

Claim Rejection –Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Claim 1 is rejected under the judicially created doctrine of the obviousness-type double patenting of claim 9 of US Pat. No.5840692. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claim 9 of 5840692 sets forth a composition comprising a polypeptide (SEQ ID NO:15) wherein the limitations for each component (Xaa_2, Xaa_3, Xaa_2, Xaa_4, Xaa_5, Xaa_6, Xaa_7, Xaa_8, Xaa_9, Xaa_{10}, Z_1 and Z_2) are the same as those set forth in the instant claim 1 formula.

Claim 9 of 5840692 is therefore an obvious variation of claim 1 of the current application and they are not patentably distinct from each other.

Claim 1 is rejected under the judicially created doctrine of the obviousness-type double patenting of claim 3 of US Pat. No.5200397. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claim 3 of 5200397 sets forth a composition comprising a polypeptide (SEQ ID NO:20) wherein the limitations for each components (Xaa_2, Xaa_3, Xaa_2, Xaa_4, Xaa_5, Xaa_6, Xaa_7, Xaa_8, Xaa_9, Xaa_{10}, Z_1 and Z_2) meet those set forth in the instant claim 1 formula.

Claim 3 of 5200397 is therefore an obvious variation of claim 1 of the current application and they are not patentably distinct from each other.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weber, Jon, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

SWL

Samuel Wei Liu, Ph.D.
Art Unit 1653, Examiner
August 4, 2004

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER